

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee 1. Charles River Laboratories, Inc.		In accordance with letter dated October 29, 2019.	4. Expiration Date: June 30, 2024
2. 54943 N. Main St. Mattawan, MI 49071		3. License number: 21-11315-02 is amended in its entirety to read as follows:	5. Docket No.: 030-08546 Reference No.:
6. Byproduct, source, and/or special nuclear material A. Any byproduct material with Atomic Numbers 1 through 83 with half-life less than or equal to 120 days B. Fluorine-18 C. Carbon-11 D. Nitrogen-13 E. Oxygen-15 F. Zirconium-89 G. Iodine-124 H. Iodine-124	7. Chemical and/or physical form A. Any B. Any C. Any D. Any E. Any F. Any G. Non-volatile H. Volatile	8. Maximum amount that licensee may possess at any one time under this license A. 50 millicuries per radionuclide and 500 millicuries total B. 10 curies total C. 5 curies total D. 1 curie total E. 2 curies total F. 2 curies total G. 2 curies total H. 1 curie total	9. Authorized use A. For research and development as defined in 10 CFR 30.4, including animal studies and in-vitro studies. B. Same as Item 9.A. C. Same as Item 9.A. D. Same as Item 9.A. E. Same as Item 9.A. F. Same as Item 9.A. G. Same as Item 9.A. H. Same as Item 9.A.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-11315-02

Amendment No. 44

Docket or Reference Number
030-08546

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
I. Iodine-125	I. Non-volatile	I. 1 curie total	I. Same as Item 9.A.
J. Iodine-125	J. Volatile	J. 350 millicuries total	J. Same as Item 9.A.
K. Copper-64	K. Any	K. 100 millicuries total	K. Same as Item 9.A.
L. Indium-111	L. Any	L. 250 millicuries total	L. Same as Item 9.A.
M. Hydrogen-3	M. Any	M. 500 millicuries total	M. Same as Item 9.A.
N. Carbon-14	N. Any	N. 840 millicuries total	N. Same as Item 9.A.
O. Calcium-45	O. Any	O. 5 millicuries total	O. Same as Item 9.A.
P. Radium-223	P. Any	P. 50 millicuries total	P. Same as Item 9.A.
Q. Thorium-227	Q. Any	Q. 50 millicuries total	Q. Same as Item 9.A.
R. Actinium-225	R. Any	R. 100 millicuries total	R. Same as Item 9.A.
S. Rhenium-186	S. Any	S. 250 millicuries total	S. Same as Item 9.A.
T. Molybdenum-99	T. Any	T. 32 curies total	T. Same as Item 9.A.
U. Technetium-99m	U. Any	U. 32 curies total	U. Same as Item 9.A.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-11315-02Docket or Reference Number
030-08546

Amendment No. 44

6. Byproduct, source,
and/or special nuclear
material

V. Cobalt-57

W. Germanium-68

X. Americium-241

Y. Cesium-137

Z. Cesium-137

7. Chemical and/or physical form

V. Sealed Sources (Eckert &
Ziegler Isotope Products d/b/a
IPL, Model 1911 and UPET
Series; International Isotopes,
Idaho, Inc., Model BM06E
Series and BM06S Series; IPL,
Model 374 Series and USM
Series)W. Sealed Sources (Eckert &
Ziegler Isotope Products d/b/a
IPL, Model 1911 and UPET
Series for
Germanium-68/Gallium-68;
International Isotopes Idaho,
Inc., Model BM06E and BM06S;
IPL, Model 374 Series and USM
Series; Siemens Medical
Solutions USA, Inc., Molecular
Imaging, Model LS)X. Calibration and Standard
Reference Sources (Eckert &
Ziegler Analytics, Model
AM1-EAB-FP)Y. Sealed Sources (Eckert &
Ziegler Analytics, Model
GF-137-D)Z. Sealed Sources (Isotope
Products Laboratories, Inc.,
Model RV-XXX)8. Maximum amount that licensee
may possess at any one time
under this license

V. 15 millicuries total

W. 5 millicuries total

X. 0.054 microcuries per
source and 0.162
microcuries total

Y. 1 millicurie total

Z. 250 microcuries total

9. Authorized use

V. Same as Item 9.A.

W. Same as Item 9.A.

X. For use in instrument calibration.

Y. For use in instrument calibration.

Z. For use in PET scanner calibration.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-11315-02

Amendment No. 44

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AA. Germanium-68	AA. Sealed Sources (Sanders Medical Products, Model PET-180/0.8)	AA. 1.5 millicuries per source and 5 millicuries total	AA. For use in PET scanner calibration.
AB. Iodine-123	AB. Non-volatile	AB. 2 curies total	AB. Same as Item 9.A.
AC. Iodine-123	AC. Volatile	AC. 1 curie total	AC. Same as Item 9.A.
AD. Cesium-137	AD. Calibration and Standard Reference Sources (Eckert & Ziegler Analytics, Model RV-137)	AD. 400 microcuries total	AD. For use in instrument calibration.
AE. Yttrium-90	AE. Any	AE. 1.6 curies total	AE. Same as Item 9.A.
AF. Cesium-137	AF. Any	AF. 5 millicuries total	AF. Same as Item 9.A.
AG. Gadolinium-153	AG. Any	AG. 800 microcuries total	AG. Same as Item 9.A.
AH. Iodine-131	AH. Any	AH. 125 millicuries total	AH. Same as Item 9.A.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 54943 N. Main St., Mattawan, Michigan, 49071.
11. The Radiation Safety Officer (RSO) for this license is Lori Ann Medeiros-Nicholson.
12. Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-11315-02

Amendment No. 44

Docket or Reference Number
030-08546

13. The licensee shall not use the licensed material in or on humans.
14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed material shall not be used for human or animal consumption.
16. This license does not authorize commercial distribution of licensed material.
17. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months, or at such other intervals as specified.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-11315-02

Amendment No. 44

Docket or Reference Number
030-08546

- E. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, *and have not been tested within the required leak test interval*, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- G. Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is authorized to collect leak test samples but not perform the analysis.
- H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for three years.
18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by U.S. Nuclear Regulatory Commission.
- B. When in use, detector cells containing a titanium tritide foil shall be vented to the outside.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for three years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
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Amendment No. 44

21. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:
- A. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.
 - B. A record of each such disposal permitted under this license condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated December 20, 2013 excluding SSDR sheets (ML13360A321)
 - B. Letter dated December 4, 2013 (ML13339A988)
 - C. Letter dated January 15, 2014 (ML14027A388)
 - D. Letter dated February 17, 2014 (ML14050A441)
 - E. Letter dated February 21, 2014 (ML14056A230)
 - F. Letter dated April 28, 2014 excluding Attachment 6, RSC Training and Experience (ML14120A163)
 - G. Letter dated April 28, 2014 excluding the MediSmarts Radiation Monitoring System Operating Manual (ML14120A167)
 - H. Letter dated June 16, 2014 (ML14169A270)

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
21-11315-02

Amendment No. 44

Docket or Reference Number
030-08546

- I. Letter dated September 8, 2014 (ML14252A338)
- J. Letter dated September 10, 2014 (ML14267A273)
- K. Letter dated March 6, 2015 (ML15071A381)
- L. Letter dated February 9, 2017 (ML17041A388)
- M. Letter dated March 29, 2018 (ML18092B265)
- N. Letter dated April 3, 2018 (ML18094A812)
- O. Letter dated April 4, 2018 (ML18096A822)
- P. Letter dated July 24, 2018 (ML18206A652)
- Q. Letter dated January 14, 2018 (ML19015A266)
- R. Letter dated December 12, 2019 (ML19350C668)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: January 21, 2020

By: _____

Frank F. D. Tran
Region 3